# Exelixis' XL184 Granted Orphan Drug Designation and Assigned the Generic Name Cabozantinib

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SOUTH SAN FRANCISCO, Calif., Jan 10, 2011 (BUSINESS WIRE) -- Exelixis, Inc. (Nasdaq:EXEL) today announced that the U.S. Food & Drug Administration (FDA) has granted orphan drug designation to XL184 for treatment of follicular, medullary, and anaplastic thyroid carcinoma, and metastatic or locally advanced papillary thyroid cancer. A pivotal phase 3 trial of XL184 is ongoing in patients with medullary thyroid cancer (MTC) and the company expects to release top-line phase 3 results in the first-half of 2011 and potentially file a New Drug Application (NDA) for the compound in the second-half of 2011. Exelixis also is evaluating XL184 in phase 2 in solid tumors including metastatic castration-resistant prostate cancer, ovarian cancer, melanoma, breast cancer, non-small cell lung cancer, and hepatocellular cancer, and in a phase 1 trial in renal cell carcinoma and differentiated thyroid cancer. Additionally, a phase 2 trial in recurrent glioblastoma is ongoing.

Orphan drug status is granted to treatments for diseases that affect fewer than 200,000 people in the U.S. and provides the benefits of extended market exclusivity for seven years, tax credits of up to 50% of the qualified clinical trial expenses and a waiver of FDA user fees.

"We are looking forward to advancing XL184 as a new potential treatment for MTC, for which we expect to file an NDA in the second half of 2011. This will be an important step toward advancing the care of patients with this cancer," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "We intend to leverage the benefits associated with orphan drug status to support our aggressive development of XL184 in a broad number of cancers. We believe this will help position us towards achieving our goals of improving outcomes for patients in some of the largest cancer indications while realizing the commercial potential of this first-in-class dual MET/VEGFR inhibitor."

**Cabozantinib Designated as Generic Name for XL184**

Exelixis also announced that the United States Adopted Name Council (USANC) and the World Health Organization's INN programme have adopted cabozantinib as the generic name for XL184. The USANC is tri-sponsored by the American Medical Association (AMA), the United States Pharmacopeial Convention (USP), and the American Pharmacists Association (APhA), and establishes drug nomenclature classifications based on pharmacological and/or chemical relationships.

**About Cabozantinib (XL184)**

Cabozantinib, an inhibitor of tumor growth, metastasis, and angiogenesis, simultaneously targets MET and VEGFR2, key kinases involved in the development and progression of many cancers. It has recently been shown in preclinical models that treatment with selective inhibitors of VEGF signaling can result in tumors that are more invasive and aggressive compared to control treatment. In preclinical studies, upregulation of MET has been shown to occur in concert with development of invasiveness after selective anti-VEGF therapy, and may constitute a mechanism of acquired or evasive resistance to agents that target VEGF signaling without inhibiting MET. Accordingly, treatment with cabozantinib in similar preclinical studies resulted in tumors that were less invasive and aggressive compared to control or selective anti-VEGF treatment. Therefore, cabozantinib has the potential for improving outcomes in a range of indications, including those where selective anti-VEGF therapy has shown minimal or no activity.

**About Exelixis**

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer. The company is leveraging its biological expertise and integrated research and development capabilities to generate a pipeline of development compounds with significant therapeutic and commercial potential for the treatment of cancer. Currently, Exelixis' broad product pipeline includes investigational compounds in phase 3, phase 2, and phase 1 clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, GlaxoSmithKline, Genentech (a wholly owned member of the Roche Group), Boehringer Ingelheim, and Daiichi-Sankyo for several compounds in its pipeline. For more information, please visit the company's web site at www.exelixis.com.

**Forward-Looking Statements**

This press release contains forward-looking statements, including, without limitation, statements related to continued development and clinical, therapeutic and commercial potential of cabozantinib (XL184), the ongoing pivotal phase 3 trial of cabozantinib in MTC and ongoing clinical trials of cabozantinib in other cancer indications, the expected release of top-line phase 3 MTC results in the first-half of 2011, the potential to file an NDA for cabozantinib in MTC in the second-half of 2011, the expected benefits to Exelixis of orphan drug status for cabozantinib, the importance of an NDA filing to Exelixis' ability to advance the care of patients with MTC and the continued development of the Exelixis pipeline, Exelixis' intent to leverage the benefits associated with orphan drug status to support its aggressive development of cabozantinib in additional cancers, and Exelixis' goals of improving outcomes for patients in some of the largest cancer indications while realizing the commercial potential of cabozantinib. Words such as "expects," "ongoing," "potential," "looking forward," "on track," "will," "intend," "goals," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing, Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion, the sufficiency of Exelixis' capital and other resources, the uncertain timing and level of expenses associated with the development of cabozantinib, the uncertainty of the FDA approval process, market competition, and changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly report on Form 10-Q for the quarter ended October 1, 2010 and Exelixis' other filings with the Securities and Exchange Commission. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis'

expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

SOURCE: Exelixis, Inc.

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